SURVEILLANCES

Quality Implementing Procedure ID: OSTI-LBNL-QIP-2.3, Rev. 0, Mod. 0 *Effective: 05/07/04*

1. PURPOSE

This Quality Implementing Procedure (QIP) describes the requirements for the conduct and documentation of quality assurance (QA) surveillances performed on Office of Science & Technology and International (OSTI)-Lawrence Berkeley National Laboratory (LBNL) Project activities.

Designated personnel from the OSTI-LBNL QA Technical Support Staff are responsible for leading the performance of surveillances in accordance with this procedure. The surveillance team may also include a scientific staff member independent of the work being surveilled, if deemed appropriate.

2. SCOPE

This QIP applies to all surveillances of OSTI-LBNL scientific processes subject to the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. This procedure applies to the Surveillance Team Lead, the QA Manager, and all participants in surveillance activities. This QIP has been developed in accordance with OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*.

3. PROCEDURE

3.1 Surveillance Preparation

3.1.1 QA Manager:

A. Together with the Deputy Project Manager (PM) (or designee), determine the need to conduct a surveillance with the following considerations:

- status and importance of the project work activity
- verify quality of work in progress
- identify conditions adverse to quality (CAQ)
- the need to verify the timely implementation, adequacy, and effectiveness of corrective actions
- identified problems or adverse trends

B. Prepare a surveillance schedule for each fiscal year.

C. Maintain the surveillance schedule including approval dates of completed surveillance reports.

D. Approve, and submit the surveillance schedule to the Records Processing Center (RPC) records at the end of the fiscal year per Section 4.0.

E. Assign surveillance numbers.

F. Assign surveillance personnel and ensure that they are knowledgeable of, and not directly responsible for, the work to be surveilled.

G. Assign surveillance teams consisting of one or more QA individuals for the performance of planned surveillances to evaluate real-time work activities. If it is determined that a scientific staff member should participate, consult with the Deputy Project Manager (or designee) regarding the assignment.

3.2 Surveillance Performance

3.2.1 Surveillance Personnel:

A. Under the guidance of the QA Manager and the assigned Surveillance Team Lead, plan surveillances based on the surveillance schedule.

B. Determine the scope and requirements for the surveillance, from such materials as procedures, plans, or checklists.

C. Inform the Principal Investigator (PI) or Responsible Individual of the surveillance date(s), the scope, and surveillance team members prior to the surveillance via memorandum or email as soon as possible.

D. Perform the surveillance through observations, reviews, and interviews with personnel performing activities.

E. Notify the QA Manager, Deputy PM, PI or Responsible Individual upon identification of a condition adverse to quality (CAQ) to permit collection of additional information or correction of the condition during the surveillance.

F. Inform the PI or Responsible Individual, the Deputy PM, and the QA Manager of the results of the surveillance, including conclusions regarding conformance, adequacy, effectiveness, and potential CAQs, at the conclusion of the surveillance.

3.3 SURVEILLANCE REPORTING

3.3.1 Surveillance Team Lead:

A. Report any conditions adverse to quality in accordance with OSTI-LBNL-QIP-16.0, *Condition Reporting and Resolution.*

B. Prepare the surveillance report in accordance with Attachment 1, Surveillance Report Instructions with input from the surveillance team members.

C. Sign and date the surveillance report.

D. Forward the surveillance report to the QA Manager.

3.3.2 QA Manager:

A. Review the surveillance report for acceptability, completeness, adherence to the procedure, instructions, and adequate identification of conditions, including satisfactory or unsatisfactory results.

B. Approve the report by signing and dating.

C. Forward the report to the PI or Responsible Individual of the surveilled activity, with copies to the PM and Deputy PM.

D. Assemble and transmit records to the Records Coordinator in accordance with Section 4.0 below.

4. RECORDS

The records listed below shall be collected and submitted to the Records Coordinator for submittal to the RPC in accordance with OSTI-LBNL-QIP-17.0, *Records Management*, as individual records or included in a records package, as specified.

4.1 QA Records

Surveillance Report Records Package:

Completed QA Surveillance Report

Formal notification documentation

Surveillance Schedule Records Package:

Approved surveillance schedule

4.2 Non-QA long-term Records

None.

4.3 Non-QA Short Term Records (three years or less retention)

None.

5. RESPONSIBILITIES

5.1 The **Deputy Project Manager (PM)** is responsible for providing the QA Manager with input regarding determination of project activities to be surveilled, and for assigning a qualified, independent scientific staff member to be a part of the surveillance team when deemed appropriate.

5.2 The **QA Manager** is responsible for determining the surveillance schedule, for assigning qualified QA staff to perform surveillance's, for oversight of surveillance activities, and approval of the surveillance report.

5.3 The **Surveillance Team Lead** is responsible for planning and conducting the surveillance activities in accordance with this procedure, and for preparing the surveillance report and any resulting CAQs.

5.4 Principal Investigator (PI) or Responsible Individual of the surveyed activity is responsible for cooperating with the surveillance team during the conduct of the surveillance, and initiating any corrective actions that can be completed during the conduct of the surveillance.

5.5 Surveillance Team Members are responsible for the preparation and the conduct of the surveillance under the guidance of the Surveillance Team Lead.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

CAQ	Condition Adverse to Quality
LBNL	Lawrence Berkeley National Laboratory
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
PM	Project Manager
PI	Principal Investigator
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description

6.2 Definitions

Condition Adverse to Quality (CAQ): A state of noncompliance with quality assurance program requirements (QARD).

Surveillance Team Lead: The Technical Support QA Staff member assigned to lead the surveillance.

Surveillance: The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness (QARD).

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LBNL-QIP-16.0, *Condition Reporting and Resolution*

OSTI-LBNL-QIP-17.0, *Records Management*

8. ATTACHMENTS

Attachment 1 - Surveillance Report Instructions

9. REVISION HISTORY

05/07/04 Revision 0, Modification 0

Initial issue.

10. APPROVALS

(Signature on File) _____ _____

Preparer: Nancy Aden-Gleason Date:

(Signature on File) _____ _____

Technical Reviewer: Yvonne Tsang Date:

(Signature on File) _____ _____

Technical Reviewer: Vivi Fissekidou Date:

(Signature on File) _____ _____

QA Reviewer: Marlene Dotterer Date:

(Signature on File) _____ _____

Project Manager: Gudmundur Bodvarsson Date:

Surveillance Report Instructions

Surveillance Team Lead:
Surveillance reports must contain the following information:

1. Identify the OSTI-LBNL Project, including project/functional or other area, that is subject to the surveillance and the location.

2. Include the dates of the surveillance activity.

3. Describe in detail, the scope of the surveillance

4. Identify or reference the requirements considered during the surveillance (QARD Sections, procedure, etc.).

5. Identify the surveillance team. Identify organization of the team and role.

6. Provide a detailed description of the activities observed, objective evidence, and applicable QARD Sections, QIPs, or TIPs. Include sufficient detail to allow a reviewer of this document to retrace the steps.

7. Identify persons and their organizations contacted during the surveillance.

8. Identify the CAQ number and provide a summary of each CAQ .

9. Provide detailed discussion of the verification of the effectiveness of previously completed corrective actions, when applicable.

10. State conclusions resulting from the surveillance. Include statements, as appropriate, in relation to the adequacy of the requirements, their implementation, and their effectiveness in meeting specified requirements.

11. Sign and date the completed surveillance report.

QA Manager:

12. Review and approve surveillance report by printing name, signing, and dating.